

CALIFORNIA STATE HEALTH AND HUMAN SERVICES AGENCY

**FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN RESEARCH
SUBJECTS**

(1) **Institution Name:**

The California Health and Human Services Agency (hereinafter known as the "Agency"). The Agency includes its Departments, (see Appendix A).

City: Sacramento

State: California

Federal Entity

Identity Identification Number (EIN), if known: 552 assures that all of its activities related to human subject research, regardless of funding sources, will be guided by the ethical principles in the following document:

The Belmont Report

(2) **Agency Compliance:**

The Agency assures that all of its activities related to Federally-supported human subject research will comply with the following procedural standards.

45 CFR 46 as stipulated in "The Terms of Assurance for Protection of Human Subjects Within the United States", provided on this date at the OHRP website.

This Agency elects to assure compliance with the Terms of Assurance for all of its human subjects research, regardless of funding source.

(3) Institutional Components:

The following are components of the Agency. All are located throughout the State of California.

Name of Component	City	State (or Country if Outside US)
California Department of Aging	Sacramento	California
California Department of Alcohol and Drug Programs	Sacramento	California
California Department of Child Support Services	Sacramento	California
California Department of Community Services and Development	Sacramento	California
California Department of Developmental Services	Sacramento	California
California Department of Health Services	Sacramento	California
California Department of Mental Health	Sacramento	California
California Department of Rehabilitation	Sacramento	California
California Department of Social Services	Sacramento	California
Emergency Medical Services Authority	Sacramento	California
Health and Human Services Data Center	Sacramento	California
Managed Risk Medical Insurance Board	Sacramento	California
Office of Statewide Health Planning and Development	Sacramento	California

(4) Operations, Procedures and Oversight Mechanisms

Institutional procedures for protecting human subjects were last updated on April 12, 2001.

These procedures include formal mechanisms for monitoring compliance with human subject protection requirements.

The institution has not established continuing programs to educate IRB members, IRB staff and research investigators about human subject protection requirements.

The Committee Chairperson, members and staff have completed the relevant OHRP modules(s) or comparable training approved by OHRP.

There are no full time positions devoted solely to human subject education activities.

This Assurance replaces MPA M-1400.

(5) Designation of Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs)

The Agency designates the following IRB for review of research on a regular basis under this Assurance at this time:

HHS IRB Registration Identifier	Name of IRB As Registered with HHS	Name and Signature of IRB Chairperson or IRB Organization Authorizing Designation of the IRB Under This Assurance.
IRB00000552	The Agency Committee for the Protection of Human Subjects	Larry Dickey, M.D., M.S.W., M.P.H.

The Agency designates no other IRBs and no IECs for review of research on a regular basis under this Assurance at this time. The Agency may, at some future date, so designate IRBs or IECs for such review. If the Agency chooses to do this, it will notify OHRP and amend this Assurance in the appropriate manner required by such designation.

(6) Committee Administrator (e.g., Human Subjects Administrator)

Contact Person:

First Name: Dennis Middle Initial: R. Last Name: Long

Degrees: M.S.W., M.P.A. Organizational Title: Administrator,
Committee for the Protection of Human Subjects

Human subject protection training last taken on: February 1, 2003

Telephone: (916) 653-0176 FAX: (916) 651-6222
E-Mail: Dlong@OSHPD.state.ca.us

Street Address: 1600 9th Street, Room 432

City: Sacramento State: CA ZIP Code: 95814

(7) Signatory Official

Acting officially and in an authorized capacity on behalf of this institution, I assure protections for human subjects as specified above. The IRBs above are designated to provide oversight for research under this Assurance. These IRBs will comply with the terms of the Assurance and possess appropriate knowledge of the local context in which this institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I have Personally satisfied the education requirements referenced in the Terms of Assurance and will require that all other relevant personnel also do so. I will further require that all such personnel receive appropriate additional initial and continuing education about human subject protection requirements.

I understand that all collaborating institutions engaged in Federally-supported human subject research must **submit their own Assurance.**

Signature _____ Date: 6/15/01

GRANTLAND JOHNSON, Secretary
California Health and Human Services Agency

(8) HHS Approval

Institution Name:

City:

State:

The Federal-wide Assurance of Protection for Human Subjects submitted to HHS by the above institution is hereby approved for the conduct of Federal sponsored research.

Signature of HHS Approving Official

Date: 7/05/2001

FWA00000681

Kamal K. Mittal, D.V.M., Ph.D.

Assurance Coordinator

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